

REMARKS

After the foregoing amendment, Claims 102, 103, 108-111, 116 and 117 are currently amended, claims 104-107, and 112-115 are cancelled. New claims 118-128 are added according to the specification. Applicant submits that new matter has not been added to the application by way of the currently added claims.

Claim Rejections - 35 U.S.C. § 112

The Examiner has rejected claims 110-117 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 102, 103, 108-111, 116 and 117 are currently amended, claims 104-107, and 112-115 are cancelled. New claims 118-128 are added according to the specification, in which no new matter has been added. The amended listing of claims substantially differentiates from the previous listing of claims and more precisely reflects the specification in the application. Therefore, Applicant respectfully traverses the Examiner's rejections under 35 U.S.C. § 112, second paragraph.

Claim Objections

The Examiner has objected claims 104-107, 110, 112 and 116 because of informalities - misspellings in each of the aforementioned claims.

Claims 102, 103, 108-111, 116 and 117 are currently amended, claims 104-107, and 112-115 are cancelled. New claims 118-128 are added according to the specification, in which no new matter has been added. Applicant submits that new listing of claims does not have misspellings or informalities.

Claim Rejections - 35 U.S.C. § 102

The Examiner has rejected claims 102, 103, and 110-115 under 35 U.S.C. §102(b or e) as being anticipated by Vanden Berghe (US 6,495,531 B2). An anticipation rejection under 35 U.S.C. §102(b or e) requires that the reference teach each and every element of the claim. Applicant respectfully traverses these rejections. However, specifically regarding the 35 U.S.C. § 102(b or e) rejections and to advance prosecution of the present application in conjunction with the following remarks presented, Claims 102, 103, 108-111, 116 and 117 are currently amended, claims 104-107, and 112-115 are cancelled. New claims 118-128 are added according to the specification, in which no

new matter has been added. The amended listing of claims substantially differentiates from the previous listing of claims and more precisely reflects the specification in the application. Therefore, Applicant respectfully traverses the Examiner's rejections under 35 U.S.C. § 102 (b or e).

Vanden Berghe discloses topical medicaments for the alleviation of itching and pain, and does not teach, suggest or disclose such a topical preparation for treatment of psoriasis, atopic dermatitis, or T-cell mediated skin disorders as claimed by Applicant. Specifically, Vanden Berghe does not teach, suggest or disclose a topical preparation comprising glucosamine at more than 10% weight in the topical preparation, which may be used for treatment of psoriasis, atopic dermatitis, or T-cell mediated skin disorders. In addition, Vanden Berghe does not teach, suggest or disclose a topical preparation for alleviation of psoriatic lesions. These psoriatic lesions include scaly plaques and eczematous lesions described in the present invention. A person of the ordinary skill in the art will understand, psoriatic lesions also include, Guttate, small red spots on the skin of some forms of psoriasis; Inverse, which occurs in armpits, groin and skin folds of some forms of psoriasis; Pustular, white blisters surrounded by red skin of some forms of psoriasis; and Erythrodermic, intense redness over

large areas of skin of some forms of psoriasis. Furthermore, *Vanden Berghe* does not teach, suggest or disclose a topical preparation for alleviation of symptoms caused by atopic dermatitis and other skin disorders induced by epidermal hyperplasia.

Vanden Berghe discloses topical medicaments that might alleviate symptoms including sore throat, tendonitis, herpes simplex infection, diaper allergy, nettle rash, arthritis urica, and eczema. However, *Vanden Berghe* does not teach, suggest or disclose a topical preparation for treatment of T-cell mediated skin disorders, which may include, as a person of ordinary skill in the art will understand, psoriasis, atopic dermatitis, many allergic skin reactions induced by insect bites or allergens, such as poison ivy and pityriasis, which are claimed by Applicant.

Furthermore, *Vanden Berghe* does not teach, suggest or disclose a topical preparation containing glucosamine that has unexpected synergistic effects on treatment of psoriasis, atopic dermatitis, and/or T-cell mediated skin disorders when the topical preparation further includes at least one herbal extract, and the at least one herbal extract may be from olive leaf, Oregon grapeseed, or witch hazel.

Therefore, based upon the present amendments and arguments, *Vanden Berghe* fails to anticipate all elements of Applicant's claimed subject matter. For at least these reasons, Applicant respectfully submits that new Claims 118-146 are allowable and requests that rejection under 35 U.S.C. §102(b) be withdrawn.

The Examiner has rejected claims 102-106, 107 and 110-115 under 35 U.S.C. §102(b) as being anticipated by *Pollock* (US 6,110,966). An anticipation rejection under 35 U.S.C. §102(b) requires that the reference teach each and every element of the claim. Applicant respectfully traverses these rejections. However, specifically regarding the 35 U.S.C. § 102(b) rejections and to advance prosecution of the present application in conjunction with the following remarks presented, Claims 102, 103, 108-111, 116 and 117 are currently amended, claims 104-107, and 112-115 are cancelled. New claims 118-128 are added according to the specification, in which no new matter has been added.

Pollock discloses a triple action complex comprising "ascorbyl glucosamine". A person of the ordinary skill in the art understands, that "ascorbyl glucosamine" is a form of Vitamin C. "Ascorbyl glucosamine" is structurely distinct from "glucosamine" and "glucosamine derivatives" disclosed by

Applicant. Glucosamine derivatives may include D-glucosamine hydrochloride, D-glucosamine sulfate, N-acetyl D-glucosamine, chitin hydrolysate, chitosan (which is composed of N-acetyl glucosamine) but not ascorbyl glucosamine. In addition, Pollock does not teach, suggest or disclose such a topical preparation for treatment of psoriasis, atopic dermatitis, or T-cell mediated skin disorders as claimed by Applicant. Specifically, Pollock does not teach, suggest or disclose a topical preparation comprising glucosamine may be used for treatment of psoriasis, atopic dermatitis, or T-cell mediated skin disorders.

Furthermore, Pollock does not teach, suggest or disclose a topical preparation containing glucosamine that has unexpected synergistic effects on treatment of psoriasis, atopic dermatitis, and/or T-cell mediated skin disorders when the topical preparation further includes at least one herbal extract from olive leaf, Oregon grapeseed, or witch hazel.

Therefore, based upon the present amendments and arguments, Pollock fails to anticipate all elements of Applicant's claimed subject matter. For at least these reasons, Applicant respectfully submits that new Claims 118-146 are allowable and requests that rejection under 35 U.S.C. §102(b) be withdrawn.

The Examiner has rejected claims 102-104, 106, 107 and 110-115 under 35 U.S.C. §102(b) as being anticipated by Schinitzki (EP 0281812). An anticipation rejection under 35 U.S.C. §102(b) requires that the reference teach each and every element of the claim. Applicant respectfully traverses these rejections. However, specifically regarding the 35 U.S.C. § 102(b) rejections and to advance prosecution of the present application in conjunction with the following remarks presented, claims 102, 103, 108-111, 116 and 117 are currently amended, claims 104-107, and 112-115 are cancelled. New claims 118-128 are added according to the specification, in which no new matter has been added. The amended listing of claims substantially differentiates from the previous listing of claims and more precisely reflects the specification in the application. Therefore, Applicant respectfully traverses the Examiner's rejections under 35 U.S.C. § 102.

Schinitzki discloses a topical therapeutic preparation for use in the treatment of acne, and does not teach, suggest or disclose such a topical preparation for treatment of psoriasis, atopic dermatitis, or T-cell mediated skin disorders, which are distinctly different from acne caused by bacteria and excess sebum. Specifically, Schinitzki does not teach, suggest or disclose a topical preparation comprising glucosamine at more

than 10% weight in the topical preparation, which may be used for treatment of psoriasis, atopic dermatitis, or T-cell mediated skin disorders. In addition, Schinitzki does not teach, suggest or disclose a topical preparation for alleviation of psoriatic lesions. These psoriatic lesions include scaly plaques and eczematous lesions described in the present invention. A person of the ordinary skill in the art will understand, psoriatic lesions also include, Guttate, small red spots on skin of some forms of psoriasis; Inverse, occurs in armpits, groin and skin folds of some forms of psoriasis; Pustular, white blisters surrounded by red skin of some forms of psoriasis; and Erythrodermic, intense redness over large areas of skin of some forms of psoriasis. Furthermore, Schinitzki does not teach, suggest or disclose a topical preparation for alleviation of symptoms caused by atopic dermatitis and other skin disorders induced by epidermal hyperplasia, but rather limits the use of his formulation to a condition caused by bacterial infection, which requires eliminating bacteria and reducing sebum.

Furthermore, Schinitzki does not teach, suggest or disclose a topical preparation containing glucosamine that has unexpected synergistic effects on treatment of psoriasis, atopic dermatitis, and/or T-cell mediated skin disorders when the

topical preparation further includes at least one herbal extract from olive leaf, Oregon grapeseed, or witch hazel.

Therefore, based upon the present amendments and arguments, Schinitski fails to anticipate all elements of Applicant's claimed subject matter. For at least these reasons, Applicant respectfully submits that new Claims 118-146 are allowable and requests that rejection under 35 U.S.C. §102(b) be withdrawn.

The Examiner has rejected claims 102-104, 108 and 110-116 under 35 U.S.C. §102(b) as being anticipated by Noel (US 5,401,773). An anticipation rejection under 35 U.S.C. §102(b) requires that the reference teach each and every element of the claim. Applicant respectfully traverses these rejections. However, specifically regarding the 35 U.S.C. § 102(b) rejections and to advance prosecution of the present application in conjunction with the following remarks presented, claims 102, 103, 108-111, 116 and 117 are currently amended, claims 104-107, and 112-115 are cancelled. New claims 118-128 are added according to the specification, in which no new matter has been added. The amended listing of claims substantially differentiates from the previous listing of claims and more precisely reflects the specification in the application.

Therefore, Applicant respectfully traverses the Examiner's rejections under 35 U.S.C. § 102.

Noel discloses a topical preparation for use in the treatment of skin suffering from greasy or seborrheic skin, comedones and acne, and does not teach, suggest or disclose such a topical preparation for treatment of psoriasis, atopic dermatitis, or T-cell mediated skin disorders as claimed by Applicant. Specifically, Noel does not teach, suggest or disclose a topical preparation comprising glucosamine at more than 10% weight in the topical preparation, which may be used for treatment of psoriasis, atopic dermatitis, or T-cell mediated skin disorders, none of which are associated with greasy skin, comedones, and acne. In addition, Noel does not teach, suggest or disclose a topical preparation for alleviation of psoriatic lesions. These psoriatic lesions include scaly plaques and eczematous lesions described in the present invention. A person of the ordinary skill in the art will understand, psoriatic lesions also include, Guttate, small red spots on skin of some forms of psoriasis; Inverse, occurs in armpits, groin and skin folds of some forms of psoriasis; Pustular, white blisters surrounded by red skin of some forms of psoriasis; and Erythrodermic, intense redness over large areas of skin of some forms of psoriasis. Furthermore, Noel does not

teach, suggest or disclose a topical preparation for alleviation of symptoms caused by atopic dermatitis and other skin disorders induced by epidermal hyperplasia.

Furthermore, Noel does not teach, suggest or disclose a topical preparation containing glucosamine that has unexpected synergistic effects on treatment of psoriasis, atopic dermatitis, and/or T-cell mediated skin disorders when the topical preparation further includes at least one herbal extract from olive leaf, Oregon grapeseed, or witch hazel.

Therefore, based upon the present amendments and arguments, Noel fails to anticipate all elements of Applicant's claimed subject matter. For at least these reasons, Applicant respectfully submits that new Claims 118-146 are allowable and requests that rejection under 35 U.S.C. §102(b) be withdrawn.

Claim Rejections - 35 U.S.C. § 103

The Examiner has rejected Claims 102-104, 106, 107 and 110-115 under 35 U.S.C. §103(a) as being unpatentable over Vanden Berghe in view of Winter (Three River Press, New York 1999). Applicant respectfully traverses these rejections.

A rejection under 35 U.S.C. § 103(a) requires that the Examiner establish a *prima facie* case of obviousness. The Examiner must show that 1) there is some suggestion or motivation, to modify the reference or to combine reference teachings; 2) there is a reasonable expectation of success; and 3) the prior art references teach or suggest all the claim limitations. Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. See MPEP § 2142 (8th ed., Rev. 2, May 2004) (citing *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)). In addition, the showings must be clear and particular and supported by objective evidence. *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002). Broad conclusory statements regarding the teaching of multiple references, standing alone, are not evidence. *Id.*

Claims 102, 103, 108-111, 116 and 117 are currently amended, claims 104-107, and 112-115 are cancelled. New claims 118-128 are added according to the specification, in which no new matter has been added. The amended listing of claims substantially differentiates from the previous listing of claims and more precisely reflects the specification in the application. Therefore, Applicant respectfully traverses the Examiner's rejections under 35 U.S.C. § 103.

The teachings of *Vanden Berghe* were set forth above. *Winter* taught that salicylic acid was useful as a keratolytic agent in a preparation of topical skin compositions. However, *Vanden Berghe* in view of *Winter* does not teach, suggest or disclose such a topical preparation for treatment of psoriasis or T-cell mediated skin disorders as claimed by Applicant. Specifically, *Vanden Berghe* in view of *Winter* does not teach, suggest or disclose a topical preparation comprising glucosamine may be used for treatment of psoriasis and T-cell mediated skin disorders.

Furthermore, *Vanden Berghe* in view of *Winter* does not teach, suggest or disclose a topical preparation containing glucosamine that has unexpected synergistic effects on treatment of psoriasis and/or T-cell mediated skin disorders when the

topical preparation further includes at least one herbal extract from olive leaf, Oregon grapeseed, or witch hazel.

The Examiner has rejected Claims 102, 103 and 108-117 under 35 U.S.C. §103(a) as being unpatentable over *Vanden Berghe* in view of *Erdelmeir* (*Planta Med* 1996; 62:241-245). Applicant respectfully traverses these rejections.

A rejection under 35 U.S.C. § 103(a) requires that the Examiner establish a *prima facie* case of obviousness. claims 102, 103, 108-111, 116 and 117 are currently amended, claims 104-107, and 112-115 are cancelled. New claims 118-128 are added according to the specification, in which no new matter has been added. The amended listing of claims substantially differentiates from the previous listing of claims and more precisely reflects the specification in the application. Therefore, Applicant respectfully traverses the Examiner's rejections under 35 U.S.C. § 103.

The teachings of *Vanden Berghe* were set forth above. *Erdelmeir* taught an antioxidant obtained from witch hazel having radical scavenging effect, as well as anti-viral and anti-inflammatory activities. However, *Vanden Berghe* in view of *Erdelmeir* does not teach, suggest or disclose such a topical preparation for treatment of psoriasis or T-cell mediated skin

disorders as claimed by Applicant. Specifically, *Vanden Berghe* in view of *Erdelmeir* does not teach, suggest or disclose a topical preparation comprising glucosamine may be used for treatment of psoriasis and T-cell mediated skin disorders.

Furthermore, *Vanden Berghe* in view of *Erdelmeir* does not teach, suggest or disclose a topical preparation containing glucosamine that has unexpected synergistic effects on treatment of psoriasis and/or T-cell mediated skin disorders when the topical preparation further includes at least one herbal extract from olive leaf, Oregon grapeseed, or witch hazel.

The Examiner has rejected Claims 102-105 and 110-115 under 35 U.S.C. §103(a) as being unpatentable over *Vanden Berghe* in view of *Navarro* (US 6,319,392 B1), and further in view of *Hebborn* (US 4,102,995). Applicant respectfully traverses these rejections.

A rejection under 35 U.S.C. § 103(a) requires that the Examiner establish a *prima facie* case of obviousness. claims 102, 103, 108-111, 116 and 117 are currently amended, claims 104-107, and 112-115 are cancelled. New claims 118-128 are added according to the specification, in which no new matter has been added. The amended listing of claims substantially differentiates from the previous listing of claims and more

precisely reflects the specification in the application. Therefore, Applicant respectfully traverses the Examiner's rejections under 35 U.S.C. § 103.

The teachings of *Vanden Berghe* were set forth above. *Navarro* taught that it was old and well known in the art to use coal tar in the making of compositions for the therapeutic treatment of skin diseases such as eczema; and *Hebborn* taught a similar effect of coal tar. However, *Vanden Berghe* in view of *Navarro*, and further in view of *Hebborn* does not teach, suggest or disclose such a topical preparation for treatment of psoriasis or T-cell mediated skin disorders as claimed by Applicant. Specifically, *Vanden Berghe* in view of *Navarro*, and further in view of *Hebborn* does not teach, suggest or disclose a topical preparation comprising glucosamine may be used for treatment of psoriasis and T-cell mediated skin disorders.

Furthermore, *Vanden Berghe* in view of *Navarro*, and further in view of *Hebborn* does not teach, suggest or disclose a topical preparation containing glucosamine that has unexpected synergistic effects on treatment of psoriasis and/or T-cell mediated skin disorders when the topical preparation further includes at least one herbal extract from olive leaf, Oregon grapeseed, or witch hazel.

The Examiner has rejected Claims 102-104, 106 and 110-115 under 35 U.S.C. §103(a) as being unpatentable over Pollock. Applicant respectfully traverses these rejections.

A rejection under 35 U.S.C. § 103(a) requires that the Examiner establish a *prima facie* case of obviousness. claims 102, 103, 108-111, 116 and 117 are currently amended, claims 104-107, and 112-115 are cancelled. New claims 118-128 are added according to the specification, in which no new matter has been added. The amended listing of claims substantially differentiates from the previous listing of claims and more precisely reflects the specification in the application. Therefore, Applicant respectfully traverses the Examiner's rejections under 35 U.S.C. § 103.

The teachings of Pollock were set forth above. Pollock discloses a triple action complex comprising "ascorbyl glucosamine". A person of the ordinary skill in the art understands, that "ascorbyl glucosamine" is a form of Vitamin C. "Ascorbyl glucosamine" is structurally distinct from "glucosamine" and "glucosamine derivatives" disclosed by Applicant. Pollock does not teach, suggest or disclose such a topical preparation for treatment of psoriasis or T-cell mediated skin disorders as claimed by Applicant. Specifically,

Pollock does not teach, suggest or disclose a topical preparation comprising glucosamine may be used for treatment of psoriasis and T-cell mediated skin disorders.

Furthermore, Pollock does not teach, suggest or disclose a topical preparation containing glucosamine that has unexpected synergistic effects on treatment of psoriasis and/or T-cell mediated skin disorders when the topical preparation further includes at least one herbal extract from olive leaf, Oregon grapeseed, or witch hazel.

The Examiner has rejected Claims 102-104, 106, 107, 108, 109 and 110-117 under 35 U.S.C. §103(a) as being unpatentable over Pollock in view of *Masaki* (Phytochemistry 1994; 37:337-343). Applicant respectfully traverses these rejections.

A rejection under 35 U.S.C. § 103(a) requires that the Examiner establish a *prima facie* case of obviousness. claims 102, 103, 108-111, 116 and 117 are currently amended, claims 104-107, and 112-115 are cancelled. New claims 118-128 are added according to the specification, in which no new matter has been added. The amended listing of claims substantially differentiates from the previous listing of claims and more precisely reflects the specification in the application.

Therefore, Applicant respectfully traverses the Examiner's rejections under 35 U.S.C. § 103.

The teachings of Pollock were set forth above. Pollock discloses a triple action complex comprising "ascorbyl glucosamine". A person of the ordinary skill in the art understands, that "ascorbyl glucosamine" is a form of Vitamin C. "Ascorbyl glucosamine" is structurely distinct from "glucosamine" and "glucosamine derivatives" disclosed by Applicant. Masaki taught an extract of witch hazel has oxygen scavenging activities. However, Pollock in view of Masaki does not teach, suggest or disclose such a topical preparation for treatment of psoriasis or T-cell mediated skin disorders as claimed by Applicant. Specifically, Pollock in view of Masaki does not teach, suggest or disclose a topical preparation comprising glucosamine may be used for treatment of psoriasis and T-cell mediated skin disorders.

Furthermore, Pollock in view of Masaki does not teach, suggest or disclose a topical preparation containing glucosamine that has unexpected synergistic effects on treatment of psoriasis and/or T-cell mediated skin disorders when the topical preparation further includes at least one herbal extract from olive leaf, Oregon grapeseed, or witch hazel.

Therefore, based upon the present amendments and arguments, the claimed invention was not *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. For at least these reasons, Applicant respectfully submits that new Claims 118-146 are allowable and requests that rejection under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicant respectfully submits that all objections and rejections have been fully addressed, that amended claims and new claims added are allowable, and that the case should be advanced to allowance.

The Applicant encourages the Examiner to call the undersigned at the telephone number indicated below if the Examiner wishes to discuss the claims or has any questions. Applicant believes that no fees are due. However, the Commissioner is hereby authorized to charge any fees or credit any overpayment to Deposit Account Number 010657 of AKIN GUMP STRAUSS HAUER & FELD, LLP.

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Respectfully submitted,



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